(3) Releases to the air of any hazardous substance from animal waste at farms.

PART 355—EMERGENCY PLANNING AND NOTIFICATION

■ 4. The authority citation for part 355 continues to read as follows:

Authority: 42 U.S.C. 11002, 11003, 11004, 11045, 11047, 11048 and 11049.

■ 5. Section 355.31 is amended by adding paragraphs (g) and (h) to read as follows:

§ 355.31 What types of releases are exempt from the emergency release notification requirements of this subpart?

(g) Any release to the air of a hazardous substance from animal waste at farms that stable or confine fewer than the numbers of animal specified in any of the following categories.

(1) 700 mature dairy cows, whether milked or dry.
(2) 1,000 veal calves.
(3) 1,000 cattle other than mature dairy cows or veal calves. Cattle includes but is not limited to heifers, steers, bulls and cow/calf pairs.
(4) 2,500 swine each weighing 55 pounds or more.
(5) 10,000 swine each weighing less than 55 pounds.
(6) 500 horses.
(7) 10,000 sheep or lambs.
(8) 55,000 turkeys.
(9) 30,000 laying hens or broilers, if the farm uses a liquid manure handling system.
(10) 125,000 chickens (other than laying hens), if the farm uses other than liquid manure handling system.
(11) 82,000 laying hens, if the farm uses other than a liquid manure handling system.
(12) 30,000 ducks (if the farm uses other than a liquid manure handling system).
(13) 5,000 ducks (if the farm uses a liquid manure handling system).

(h) Any release to the air of a hazardous substance from animal waste at farms from animals that are not stabled or otherwise confined.

■ 6. Section 355.61 is amended by adding in alphabetical order the definitions of “Animal waste” and “Farm” to read as follows:

§ 355.61 How are key words in this part defined?

Animal Waste means manure (feces, urine, and other excrement produced by livestock), digestive emissions, and urea. The definition includes animal waste when mixed or commingled with bedding, compost, feed, soil and other typical materials found with animal waste.

Farm means a facility on a tract of land devoted to the production of crops or raising of animals, including fish, which produced and sold, or normally would have produced and sold, $1,000 or more of agricultural products during a year.

SUPPLEMENTARY INFORMATION:

I. Issuance of a Proposed Rule

On May 23, 2008 (73 FR 30030), the Department of Health and Human Services (the Department) published in the Federal Register a proposed rule with a 60-day comment period that described the reporting requirements that we proposed to require of all insurers that issue qualified long-term care insurance policies under the State Long-Term Care Partnership Program.

The proposed rule and this final rule describe the reporting requirements that the Department is requiring of all insurers that issue long-term care insurance policies under a State Long-Term Care Partnership Program for a State with as Medicaid State plan amendment approved as of May 14, 1993. We point out that neither the proposed rule nor this final rule requires participating insurers to report data from States with a Partnership State Reciprocity agreement whereby States can provide Medicaid asset disregards for
Partnership policies purchased in other States.

Comment: One commenter suggested that language be added in the final rule to make clear that insurers are not required by the regulation to report Partnership data to the Department for States with a Partnership Medicaid State plan amendment approved as of May 14, 1993.

Response: We have added language above and in other applicable sections of this final rule, as the commenter suggested, to make clear the nonapplicability of the reporting requirements for submission of Partnership data by insurers in States with a Partnership Medicaid State plan amendment approved as of May 14, 1993.

III. Background

A. Historical Overview of State Long-Term Care Partnership Programs

1. Initial Development of Programs

In the late 1980’s, a number of State Medicaid programs began to work with private insurance companies to create a bridge between Medicaid and insurance for long-term care. The goal of these collaborations was to create private insurance policies that were more affordable and provide better financial protection to consumers against large liabilities for long-term care costs than the policies generally available at that time. The result of these collaborations was the establishment of the State Long-Term Care Partnership Program that provided for expanded access to Medicaid by allowing applicants who use long-term care insurance policies to have higher assets and still be eligible for Medicaid, as long as they meet all other Medicaid eligibility criteria. The first four States that implemented Partnership programs, in 1993 (California, Connecticut, Indiana, and New York), used two different methods for determining the amount of assets a participant was allowed to keep. Three States allowed participants to keep an amount equivalent to the amount paid by the insurance policy on his or her behalf (known as the “dollar-for-dollar approach”). The other State required the purchase of a more comprehensive policy and, in exchange, allowed participants to keep all of their assets (known as the “total assets approach”). Over time, one State combined these models to create a hybrid approach in which participants purchasing and using a policy that would cover fewer than 4 years of benefits would be allowed to keep one dollar for every dollar of paid benefits and those participants purchasing and using a policy that would cover 4 or more years of benefits would be allowed to keep all of their assets. These State partnership programs provided an incentive for insurers to offer affordable, high-quality benefits and for consumers to protect themselves against the high cost of long-term care through the purchase of insurance policies that can be used in conjunction with benefits provided under Medicaid.

As part of the implementation process, each of the four States that initially implemented Partnership programs in 1993 outlined a set of data reporting requirements for participating insurers. The data that were to be collected were intended to allow each State to monitor program activities and evaluate the impact of the Partnership Program on Medicaid long-term care expenditures. The insurers who participated in these partnerships recommended, as part of the design of the data collection requirements, that the participating States use a unified set of reporting requirements to streamline the reporting burden on the participating insurers. The participating insurers believed that if each State designed its own reporting requirements, the administrative costs for the program would be prohibitive. The four States agreed with the participating insurers and adopted a uniform set of reporting criteria. The four initial States launched their Partnership programs using existing State authority through amendments to their State Medicaid plans (Partnership Medicaid State plan amendments). Each State requested a change in the treatment of assets in the Medicaid financial eligibility test. No other Federal authority was necessary at that time to operate the programs.

Comment: One commenter suggested that language be added to the Background section of the final rule to make clear that consumers who take advantage of the Partnership Program must also meet all other Medicaid eligibility requirements. Two commenters suggested that the discussion of the amount of asset protection offered under the original Partnership Programs be expanded in the final rule to reflect the differences between the “dollar-for-dollar model” and the “total assets model.”

Response: We have added language above in this final rule, as the commenters suggested, to specify that consumers who take advantage of the Partnership Program must also meet all other Medicaid eligibility requirements and to express differences between the “dollar-for-dollar model” and the “total assets model.”

2. Omnibus Budget Reconciliation Act of 1993

The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993), Public Law 103–66, contained language that changed the conditions under which Medicaid State plan amendments relating to asset disregards for private long-term care insurance could be approved. OBRA 1993 allowed California, Connecticut, Indiana, and New York, as well as Iowa and Massachusetts, to continue their initial Long-Term Care Partnership Programs. However, OBRA 1993 specified a set of requirements for any additional States that chose to operate a Partnership Program. Any State, other than the initial four partnership States, that sought a Medicaid State plan amendment on or after May 14, 1993, was required to abide by the following additional conditions:

a. Estate Recovery

States establishing Long-Term Care Partnership Programs on or after May 14, 1993, were required to recover from the estates of Medicaid recipients in States with partnership agreements expenses incurred for the provision of long-term health care under Medicaid. Assets that were disregarded in the initial financial eligibility process were also exempt from estate recovery in the initial four States with Partnership Programs. States establishing new Partnership Programs were only allowed to disregard assets in the initial eligibility process but not in the estate recovery process. After a Medicaid recipient who had a long-term care insurance policy issued under a State
Long-Term Partnership Program died, the State was required to recover an amount equivalent to what Medicaid spent on his or her behalf from the deceased recipient’s estate, including any protected assets under the State Long-Term Care Partnership Program.

b. No Waiver of Estate Recovery

States establishing Long-Term Care Partnership Programs on or after May 14, 1993, were precluded from waiving the estate recovery requirement for Medicaid recipients who had obtained long-term care insurance policies issued under a State Long-Term Care Partnership Program. This definition was more expansive than the definition that was generally used by States.

While OBRA 1993 did not forbid additional States from attempting to establish new Long-Term Care Partnership Programs under the new conditions, the impact was essentially the same as a ban. A few States tried unsuccessfully to launch partnership programs under the new conditions. Other interested States passed enabling legislation with contingency language that allowed the State to proceed if the OBRA 1993 partnership provisions were repealed. No subsequent Federal legislation related to the Long-Term Care Partnership Programs was enacted until the Deficit Reduction Act of 2005 (DRA) Public Law 109–171. As discussed in detail under section II.A.3. of this proposed rule and under section III.A.3. of this final rule, the DRA included provisions that allow States to offer specific asset disregards for Medicaid eligibility purposes under a new set of conditions.

3. Deficit Reduction Act of 2005

Section 6021(a)(1) of the DRA amended section 1917(b)(1)(C)(i) of the Act and added new sections 1917(b)(1)(C)(iii) through (vi) to the Act that provide for an expansion of the State Long-Term Care Insurance Partnership Program through a new set of conditions. These conditions pertain to States with Medicaid State plan amendments approved after May 14, 1993. Under this provision, States may establish “qualified State long-term care insurance partnerships”, defined in the Act as an approved Medicaid State plan amendment under Title XIX of the Act that provides for the disregard of any assets or resources in an amount equal to the insurance benefit payments that are made to or on behalf of an individual who is a beneficiary under a long-term care insurance policy if certain requirements specified in sections 1917(b)(1)(C)(iii) through (VII) of the Act are met. In other words, States establishing new Partnership programs must offer a dollar of asset disregard for every dollar paid out under a long-term care insurance policy issued under that State’s long-term care partnership program.

Section 1917(b)(1)(C)(iii) of the Act provides that the insurance policy must be a qualified long-term care insurance policy as defined in section 7702B(b) of the Internal Revenue Code of 1986, that is issued not earlier than the effective date of the State plan amendment. (If an individual has an existing long-term care insurance policy that does not qualify as a qualified partnership policy due to the issue date of the policy, and that policy is exchanged for another policy, the State insurance commissioner or other State authority must determine the issue date for the policy that is received in exchange. Under this provision, a long-term care insurance policy includes a certificate issued under a group insurance contract.)

Among other requirements specified in that statute for qualified long-term care insurance partnerships:

- The long-term care insurance policy must (1) be issued to an insured individual who is a resident of the State in which coverage first became effective under the policy (sections 1917(b)(1)(C)(iii)(I) of the Act); (2) be certified by the State insurance commissioner or other appropriate authority that the policy meets specific provisions of the National Association of Insurance Commissioners (NAIC) October 2000 Model Regulation and Model Act (sections 1917(b)(1)(C)(iii)(III) and 1917(b)(5)(B) of the Act); and (3) include certain protections against inflation on an annual basis (section 1917(b)(1)(C)(iii)(IV) of the Act).

- The State Medicaid agency must provide information and technical assistance to the State insurance department on the insurance department’s role of assuring that any individual who sells a long-term care insurance policy under the partnership receives training and demonstrates evidence of an understanding of such policies and how they relate to other public and private coverage of long-term care (section 1917(b)(1)(C)(iii)(V) of the Act).

- Issuers of long-term care insurance policies under a State qualified long-term care insurance partnership must provide regular reports to the Secretary, in accordance with regulations of the Secretary, that include notification regarding when benefits provided under the policy have been paid and the amount of such benefits paid, notification regarding when the policy otherwise terminates, and such other information as the Secretary determines may be appropriate to the administration of State long-term care insurance partnerships (section 1917(b)(1)(C)(iii)(VI) of the Act). Section 1917(b)(1)(C)(iv) of the Act provides that the regulations required under section 1917(b)(1)(C)(iii)(VI) of the Act shall be promulgated after consultation with the NAIC, issuers of long-term care insurance policies, States with experience with long-term care insurance partnership plans, other States, and representatives of consumers of long-term care insurance policies, and shall specify the type and format of the data to be reported and the frequency with which such reports are to be made. In addition, the Secretary, as appropriate, shall provide copies of the reports provided in accordance with that clause to the State involved.

- The State may not impose any requirement affecting the terms of benefits of a policy under the partnership program unless the State imposes such requirement on long-term care insurance policies without regard to whether the policy is covered under the partnership or is offered in connection with such a partnership (section 1917(b)(1)(C)(iii)(VIII) of the Act).

Section 1917(b)(1)(C)(iv) of the Act provides that a State that had a State plan amendment approved as of May 14, 1993, satisfies the requirements of the statute under clause (II) and may continue operating as originally implemented if the Secretary determines that the State Medicaid plan amendment provides for consumer protection standards that are no less stringent than the consumer protection standards that applied under such a State plan amendment as of December 31, 2005.

Comment: One commenter requested that the language that describes the impact of the DRA of 2005 be modified in the final rule to clearly indicate that the conditions set forth in section 6021(a) through (c) of the DRA of 2005 pertain only to States with Partnership
Medicaid State plan amendments approved after May 14, 1993. One commenter suggested that the description of the “grandfathered” States also make clear that the regulations do not pertain to States with a Partnership Medicaid State plan amendment approved as of May 14, 1993.

Response: We have added language above and in other applicable sections in this final rule, to make these clarifications, as suggested by the commenter.

B. Implementing Regulations

Currently, there are no Federal regulations directly related to State operation of State Long-Term Care Partnership Programs. In 2006, the Department provided guidance to States, through a letter to Medicaid Directors, on the implementation of State long-term care partnership programs under the DRA. In areas in which the program coordinates benefits with Medicaid coverage of long-term care, the existing Medicaid regulations at 42 CFR Chapter IV, Subchapter C, are applicable. In 2006, States were provided with guidance on the implementation of State Long-Term Care Partnership Programs under the DRA of 2005.

To implement section 1917(b)(1)(C)(iii)(VI) and 1917(b)(1)(C)(v) of the Act, as directed by the statute, in the May 23, 2008 proposed rule (73 FR 30033), we proposed to set forth in regulations the requirements for reporting information and data on qualified long-term care insurance policies issued under State Long-Term Care Partnership Programs under an approved State plan amendment. In this final rule, we are adopting the regulations as final with some technical changes, as discussed below.

C. States Currently Operating Long-Term Care Partnership Programs

California, Connecticut, Indiana, Iowa, Massachusetts, and New York had approved State Long-Term Partnership Programs under an approved State plan amendment as of May 14, 1993. They were “grandfathered” as satisfying the statutorily imposed requirements when, pursuant to section 1917(b)(1)(C)(iv) of the Act, the Secretary determined that the State plan amendments of these States provide protection no less stringent than that applied under their State plan amendments as of December 31, 2005.

At the same we issued the proposed rule, we stated that, as of December 2007, seven other States offered State Long-Term Care Partnership policies for sale under the DRA provisions: Florida, Idaho, Kansas, Minnesota, Nebraska, South Dakota, and Virginia. Nine States had approved State plan amendments for qualified State Long-Term Care Partnership Programs although policies had not yet been issued pursuant to those programs: Colorado, Florida, Georgia, Iowa, Minnesota, Missouri, North Dakota, Nevada, Ohio, and Oregon. Four States had submitted State plan amendments for which approval is pending: Arizona, New Hampshire, Oklahoma, and Pennsylvania. Ten other States were in the process of developing Partnership Programs: Illinois, Maine, Maryland, Michigan, Montana, New Jersey, Rhode Island, Texas, Vermont, and Wisconsin.

As of August 2008, Partnership policies are still for sale in the four States that first implemented a Partnership program, as well as in 13 additional States. Nine States have approved Medicaid State plan amendments, although policies are not yet for sale. Three other States have Medicaid State plan amendments pending approval from the Centers for Medicare and Medicaid, HHS.

IV. Provisions of the Proposed Rule and This Final Rule

A. Legislative Authority

As stated earlier, the DRA of 2005 requires insurers participating in State long-term care partnership programs to provide regular reports to the Secretary in a manner in accordance with regulations of the Secretary. The reports must include notification regarding when benefits provided under the policy have been paid and the amount of the benefits paid, notification regarding when the policy otherwise terminates, and any other information as the Secretary determines may be appropriate to the administration of State long-term care insurance partnerships. Section 1917(b)(1)(C)(v) of the Act provides that the regulations required under section 1917(b)(1)(C)(iii)(VI) of the Act must be promulgated after consultation with the NAIC, issuers of long-term care insurance policies, States with experience with long-term care insurance partnership plans, other States, and representatives of consumers of long-term care insurance policies, and must specify the type and format of the data to be reported and the frequency with which the reports are to be made. In addition, the Secretary, as appropriate, must provide copies of the reports provided in accordance with that clause to the State involved.

B. Collaboration With States, Insurers, Insurance Regulators, and Consumers in the Development of Reporting Requirements

In accordance with section 1917(b)(1)(C)(v) of the Act, as added by the DRA of 2005, as we discussed in the proposed rule, we have consulted with numerous stakeholders in the development of the reporting requirements presented in this rule. In addition to one-on-one consultations with stakeholders representing States, insurers, consumers, and regulators, we have established a Technical Expert Panel to provide a forum for the exchange of ideas, perspectives, and expertise regarding the specification of individual data items. The Technical Expert Panel consists of approximately 25 members representing insurers, States, consumer organizations, the NAIC, the Federal Government, and the policy research community. The panel members were selected in January 2007, from responses to invitations sent by HHS along with an initial draft of the reporting requirements. We held numerous meetings and teleconferences with the panel members to discuss and further develop the draft reporting requirements and to obtain further input on partnership implementation. The reporting requirements presented in the proposed rule and finalized in this final rule represent the product of this ongoing stakeholder input process. We plan to continue ongoing work with the Technical Expert Panel.

C. Incorporation of Reporting Requirements in the Code of Federal Regulations

In the proposed rule, the Department proposed to establish under Title 45, Part 144 of the Code of Federal Regulations a new Subpart B to incorporate the requirements for the reporting of data by insurers on qualified long-term care insurance policies issued under State Long-Term Care Partnership Programs that are established under an approved Medicaid State plan amendment. Specifically—

Proposed § 144.200, which contained the basis for the regulations.

Proposed § 144.202, which included the definitions used throughout the subpart.

Proposed § 144.204, which specified the applicability of the regulations under the subpart.

Proposed § 144.206, which specified the requirements for reporting of long-term care partnership program data and the frequency with which insurers must report the data.
Proposed § 144.208, which specified the deadlines for submission of reports.
Proposed § 144.210, which specified the format and manner in which the data are to be reported.
Proposed § 144.212, which specified the confidentiality of information requirements that will be applied.
Proposed § 144.214, which specified the action that the Secretary will take if an insurer fails to report the required data by the specified deadlines.

Under proposed § 144.202, Definitions, we included the following definitions:

**Partnership qualified policy** refers to a qualified long-term care insurance policy issued under a qualified State long-term care insurance partnership.

**Qualified long-term care insurance policy** means an insurance policy that has been determined by a State insurance commissioner to meet the requirements of sections 1917(b)(1)(C)(iii) through (iv) and 1917(b)(5) of the Act. It includes a certificate issued under a group insurance contract.

**Qualified State long-term care insurance partnership** means an approved Medicaid State plan amendment that provides for the disregard of any assets or resources in an amount equal to the insurance benefit payments that are made to or on behalf of an individual who is a beneficiary under a long-term care insurance policy that has been determined by a state insurance commissioner to meet the requirements of section 1917(b)(1)(C)(iii) of the Act [incorrectly cited in the proposed rule as section 1917(b)(a)(C)(iii)]. It includes any Medicaid State plan amendment approved as of May 14, 1993 [incorrectly stated in the proposed rule as May 4, 1993], that meets the requirements of section 1917(b)(1)(C)(iii) of the Act and for which the Secretary determined that the State plan amendments provides for consumer protection standards that are no less stringent than the consumer protection standards that applied under the State plan amendment as of December 31, 2005.

Comment: The commenter suggested that the word “care” be inserted into the definition of “Partnership qualified policy.” One commenter pointed out that we had reversed the order of two words and therefore incorrectly labeled the definition of “qualified long-term care insurance policy” as “qualified long-term care insurance policy.”

Response: We agree with the first commenter’s suggestion and have revised the definition of “Partnership qualified policy” in this final rule to refer to a qualified long-term care insurance policy issued under a qualified State long-term care insurance partnership. We thank the commenter for bringing to our attention the inadvertent mislabeling of the definition of “qualified long-term care insurance policy” and have made the correction in this final rule.

Comment: One commenter suggested that the definition of a “Qualified State long-term care insurance partnership” be modified to clarify that the regulations do not require insurers to report Partnership data to the Department for States with a Partnership Medicaid State plan amendment approved as of May 14, 1993.

Response: In response to the commenter’s suggestions, we have revised the proposed definition for “Qualified State long-term care insurance partnership”, by removing the last sentence of the definition, to clarify that the regulations do not require insurers to report Partnership data to the Department for States with a Partnership Medicaid State plan amendment approved as of May 14, 1993.

After consideration of the public comments received, we are adopting as final proposed §§ 144.200, 144.202, and 144.204, with the following modifications. We have revised the definition of “Partnership qualified policy” by adding the word “care” in the definition. We have corrected the inadvertent mislabeling of the definition of “Qualified long-term care insurance policy.” We have revised the definition of “Qualified State long-term care partnership” by removing the last sentence of the proposed definition. Each of the additional proposed regulatory requirements is discussed in detail in the sections below.

### D. Specific Reporting Requirements

As discussed in the proposed rule, in consultation with stakeholders and the Technical Expert Panel, we developed requirements for insurers for reporting data under the State Long-Term Care Partnership Program under two categories: (1) Registry data; and (2) claims data (proposed § 144.206).

We proposed that these two categories would require the submission of data in four distinct file types. Generally, participating long-term care insurers will report under only two of these files. For all four file types, as we proposed, we are requiring insurers to report on only those insured individuals, policyholders, and claimants who have active qualified long-term care insurance partnership policies or certificates. The reporting requirements will not apply to insurance policies or certificates that are not partnership qualified.

Insurer reporting specifications are detailed in an HHS document entitled “State Long-Term Care Partnership Insurer Reporting Requirements” which we expect will be available via the Internet at the Web site at: [http://aspe.hhs.gov/daltcp/PartRepReq.pdf](http://aspe.hhs.gov/daltcp/PartRepReq.pdf). As announced, the document would be available by June 1, 2008. However, the release date has been delayed.) We are in the process of developing an integrated database through which insurers will submit these data. As we proposed, we are requiring that data be submitted through a secure Web site that meets all current Health Insurance Portability and Accountability Act requirements for security of personal health information.

#### 1. Registry Data

In the proposed rule (73 FR 30034), we proposed to require insurers to report data, on a semiannual basis, on all insured individuals who have been issued qualified long-term care insurance policies or certificates under qualified State Long-Term Care Partnership Programs; that is, for the 6-month reporting periods of January 1 through June 30 and July 1 through December 31 of each year (proposed § 144.206(b)(1)(iii)). We proposed that the reports must include data on qualified long-term care insurance partnership policies sold on either an individual basis or a group basis, as long as individual-level data are available to the insurer. Under proposed § 144.206(b)(1)(iii), these data would include, but are not limited to, the following:

- Current identifying information on each insured individual.
- The name of the insurance company and the issuing State.
- The effective date and terms of coverage under the policy.
- The coverage period and benefits.
- The annual premiums.
- Other information as specified by the Secretary in “State Long-Term Care Insurance Partnership Insurer Reporting Requirements.”

Comment: One commenter pointed out that we used different terminology in the proposed rule to describe the instruction document we would issue for reporting data.

Response: We thank the commenter for bringing this inconsistency to our attention. In the proposed rule, we inconsistently used the term “Reporting
the end of the reporting period registry data reports was 30 days after proposed deadline for submittal of different reporting periods, depending upon the file type. After consideration of the public comments received, we are adopting as final our proposed § 144.206 with one technical change to the title of the instruction document, as discussed above.

2. Claims Data

In the proposed rule, we proposed to require insurers to report data, for each quarter of the calendar year, on all benefit claims paid for all insured individuals who have been issued qualified long-term care insurance policies or certificates (individual policies or under group coverage plans) under qualified State Long-Term Care Partnership Programs (proposed § 144.206(b)(2)). Under proposed § 144.206(b)(2)(ii), these data would include, but are not limited to, the following:

- Current identifying information on the insured individual.
- The type and cash amount of the benefits paid during the reporting period and lifetime to date.
- Remaining lifetime benefits.
- Other information as specified by the Secretary in “State Long-Term Care Insurance Partnership Insurer Reporting Requirements.”

We did not receive any public comments on this section other than the notification that we had used different titles for the instruction document discussed above. Therefore, we are adopting as final the proposed provisions of § 144.206 with the technical change noted above.

3. Frequency of Reports and Deadlines for Submission

In the proposed rule, we proposed to require insurers to submit data for different reporting periods, depending upon the file type.

We proposed to require insurers to submit the required registry data to the Secretary on a semiannual basis; that is, for the 6-month reporting period of January 1 through June 30 and July 1 through December 31 of each year under proposed § 144.206(b)(1)(i). The proposed deadline for submittal of registry data reports was 30 days after the end of the reporting period (proposed § 144.208(b)).

Comment: One commenter stated that the discussion of frequency of reports in the preamble of the proposed rule failed to list the frequency of the reports on insurance claims.

Response: The commenter is correct. Even though we specified the frequency of the reports on insurance claims data in the regulation text under proposed § 144.208(c), we did not include a detailed discussion in the preamble. The description of the submission of the claims data along with a reference to the detailed documentation of the reporting requirements is as follows:

We are requiring insurers to submit the required claims data to the Secretary on a quarterly basis; that is, for the 3-month reporting period of January 1 through March 30, April 1 through June 30, July 1 through September 30, and, October 1 through December 31 of each year under § 144.206(b)(2)(i). The deadline for submittal of claims data reports is 30 days after the end of the reporting period (§ 144.208(c)). Detailed reporting instructions can be found on the Internet at the Web site: http://aspe.hhs.gov/daltcp/reports/2008/PartRepReq.pdf.

After consideration of the public comments received, we are adopting as final proposed §§ 144.208(b) and (c) without modification.

4. Transition Provision

For insurers who have issued or exchanged a qualified Partnership policy prior to the effective date of the final regulations we issue, we proposed a transition provision under § 144.208(a). We proposed that the first reports required for these insurers would be the reports that pertain to the reporting period that begins no more than 120 days after the effective date of the final regulations.

We did not receive any public comments on the proposed § 144.208(a). Therefore, we are adopting it as final without modification in this final rule.

5. Format and Manner of Reporting Data

In the proposed rule, we proposed to require that insurers submit the required data in the format and manner specified by the Secretary in the HHS-issued insurer reporting specifications document, “State Long-Term Care Insurance Partnership Insurer Reporting Requirements” (proposed § 144.210). As we mentioned earlier, we are in the process of developing an integrated database that would be accessible through a secure Web site, and we plan to issue instruction Web pages to show insurers how they will access and input the required data into the HHS reporting system.

We did not receive any public comments on the proposed § 144.210. Therefore, we are adopting it as final without modification in this final rule.

6. Use of Submitted Reports

As we discussed in the proposed rule, the overall purpose of the data is twofold: First, to be used in efforts to monitor program performance at both the State and Federal level; and second, to provide data for a longer term evaluation of the effectiveness of the Partnership Program. The Department and the States participating in the State Long-Term Care Partnership Program will use the information provided by insurers in compliance with the reporting requirements for analytical studies and for program monitoring. The data provided by insurers will reflect the combined experience of all State Long-Term Care Partnership Programs in terms of policies sold and benefits used. We plan to use the data to produce reports for Congress and other interested stakeholders on the implementation of the State Long-Term Care Partnership Program. In addition, we plan to use the data to generate individual State-level reports that will be used by the States to track the implementation of the Partnership Program at the State level. The Department may also use the data to examine public policy issues related to long-term care insurance in general as opportunities arise.

HHS does not intend to use the data to determine asset disregard levels for individuals who participate in the State Long-Term Care Partnership Program and eventually apply for Medicaid coverage. We will not collect data on “point in time” information regarding the amount of insurance benefits used by claimants, or exact information on when private insurance benefits may be exhausted, which clearly would depend upon how claimants use benefits to purchase long-term care services. The computation of asset disregard levels and the determination of Medicaid eligibility coverage are matters that will be dealt with among the insurer, the insured individual, and the State Medicaid eligibility office. We expect that when insured individuals exhaust their insurance coverage (or otherwise become eligible for Medicaid prior to the exhaustion of benefits), insurers will provide them with documentation of their participation in the State Long-Term Care Partnership Program and of the amount of benefits that the insured received. This documentation will become part of the insurers documentation provided by the insured individual at the time he or she applies for Medicaid.
The Medicaid eligibility office will then determine, based upon the documentation provided by the applicant, the asset disregard level that will be applied.

It is possible that State Medicaid programs may wish to access the collected data for monitoring purposes, to help them anticipate the number of insured individuals who may become eligible for Medicaid asset disregards over a projected time period. For example, through reports provided to each State from the integrated database, States would know how many partnership policyholders are “in claim” during any 3-month reporting period. States would also know, approximately, to what extent policyholders who are in claim have utilized the insurance benefits for which they are eligible and the amount of benefits remaining under their policy maximums. However, once an insured individual uses his or her insurance benefits under the policy, his or her eligibility for Medicaid will still depend upon the amount of available assets he or she retains, relative to his or her asset disregard, as well as other Medicaid eligibility criteria. For example, an insured individual may be eligible for an asset disregard of $150,000, but still retains $250,000 in countable assets. In this case, he or she would have to spend down $100,000 of his or her available assets before applying for Medicaid coverage. Thus, in general terms, States will be able to use the data to project future applications for Medicaid (and their potential budgetary impacts) but, at the individual level, the specific financial circumstances of each insured individual would determine his or her eligibility for Medicaid coverage.

Comment: One commenter suggested that the Department consider a broader use of the data to investigate a number of issues related to long-term care insurance in general as well as issues related to the Partnership Program.

Response: The Department will explore using the Partnership data to examine other issues related to long-term care insurance, to the extent possible. We have modified the preamble discussion above to indicate this.

Comment: One commenter suggested that the language included in this section of the preamble of the proposed rule could imply that participants must exhaust their benefits before they can take advantage of the Partnership Program.

Response: The commenter is correct in asserting that exhaustion of benefits is not required by the DRA of 2005. Participants may apply for a Medicaid asset disregard before they have exhausted their insurance benefits. We have modified the preamble language in this final rule to reflect the possibility that someone may apply for Medicaid and seek an asset disregard before they have exhausted their insurance benefits.

E. Additional State-Manded Reporting Requirements

The DRA of 2005 explicitly states that there is nothing in the statute that prohibits States from imposing additional reporting requirements on insurers participating in the Long-Term Care Partnership Program, beyond the Federal reporting requirements that we proposed in the proposed rule and are finalizing in this final rule. This regulation does not require insurers to report Partnership data to the Department for States with a Partnership Medicaid State plan amendment as May 14, 1993. However, we believe that the information that will be made available to the Secretary and the States in the Long-Term Care Partnership Program through these mandated reporting requirements will be sufficient to meet the policy analysis and program monitoring needs of the States. We, as well as the stakeholders participating in the development of these reporting requirements, attempted to achieve a proper balance between the legitimate needs of the Federal Government and State governments to monitor the implementation and operation of the State Long-Term Care Partnership Program, and the desire not to impose undue cost burdens on participating insurers, to the point where they may consider it not economically beneficial to participate in the Partnership Program.

Comment: One commenter suggested that the discussion of State-mandated reporting in the final rule be revised to clarify that nothing in the regulation prohibits any State (including grandfathered States) from requiring data from participating Partnership insurers. The commenter further suggested that the section describe the motivations of States for requiring State-specific data. The commenter also suggested that all references to costs of data collection on the part of insurers be deleted. The commenter stated that the costs of reporting are “often minimal or nonexistent.”

Response: We are not modifying the language in this section as the commenter suggested. The balance between the Government’s need for data and the cost burden on participating insurers is, in our view, a real issue, especially given the varying size of different participating States. Finding a balance between the need for data and the cost burden was part of the charge given to the stakeholder group mandated by the DRA. We believe the discussion of the costs of data collection in this section is appropriate and that its presence does not diminish States’ ability to negotiate for State-specific data.

F. Confidentiality of Information

In the proposed rule, we proposed to provide in the regulations that the data collected and reported under the requirements of the regulations would be subject to the confidentiality of information requirements specified in regulations under 42 CFR Part 401, Subpart B, and 45 CFR Part 5, Subpart F and any other applicable confidentiality statute or regulation (proposed § 144.212).

We did not receive any public comments on this section. Therefore, we are adopting as final the proposed § 144.212 without modification in this final rule.

G. Actions for Noncompliance With Reporting Requirements

In the proposed rule, we proposed under § 144.214 that if an insurer of a qualified long-term care insurance policy does not submit the required reports by the due dates specified in the new subpart B of 45 CFR Part 144, the Secretary notifies the appropriate State insurance commissioner within 45 days after the deadline for submission of the information and data specified in § 144.208.

We did not receive any comments on this proposed section. Therefore, we are adopting as final the proposed § 144.214 without modification.

H. Provision of Reports to Partnership States

Section 1917(b)(1)(C)(v) of the Act provides that the Secretary, as appropriate, must provide copies of the reports provided by insurers to the State involved. We plan to make reports containing the reported data available to States in a timely and efficient manner.

V. Collection of Information Requirements

The Department of Health and Human Services has determined that this notice of proposed rulemaking contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). In compliance with the requirements of section 3506(c)(2)(A) of the PRA, the Office of the Secretary...
We indicated that public comments addressed as a result of the notice in the proposed rule would be taken into account in the formal OMB request for clearance for this data collection. The information collection provisions in this final rule have been approved by OMB under OMB control number 0990–0333, effective through December 31, 2011.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

B. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

While we have determined that this final rule is not economically significant, it is, however, a significant regulatory action. We estimate that the aggregate cost to participating private insurers of implementing the reporting requirements in this final rule will be approximately $1.5 million.

C. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most insurance companies are not considered to be small entities because they generally have revenues of more than $29 million in any 1 year. (For details, see the Small Business Administration’s final rule that sets forth size standards for industries at 65 FR 69432, November 17, 2000.) For purposes of the RFA, all insurance companies are not considered to be small entities. Individuals and States are not included in the definition of a small entity. However, we solicited comments on our estimates and analysis of the impact on insurers of the proposed rule.

There are approximately 100 insurance companies located nationwide that issue long-term care insurance policies. We expect that, of these 100 companies, approximately 30 insurance companies will participate in qualified State Long-Term Care Partnership Programs. Currently, there are 15 to 20 companies operating in States that are selling or have issued qualified long-term care insurance policies under the State Long-Term Care Partnership Programs. As of December 2007, approximately 300,000 policies have been sold. We believe this represents approximately 80 percent of the policies that might be sold when the Partnership Programs are established nationwide. We anticipate that the number of insurance companies selling qualified long-term care insurance benefits used. Data from this submission will be provided to State Medicaid agencies to assist in determining the amount of asset protection earned by program participants.

Comment: One commenter brought to our attention two technical errors in the narrative portion of the instruction document and another error in the detailed data element specifications.

Response: We have made the appropriate changes to the instruction document, which is now listed as Version 1.1. This instruction document is available on the Web site at: http://aspe.hhs.gov/daltcp/reports/2008/PartRepReg.pdf.

It is estimated that insurers participating in the Partnership Program will be able to provide the necessary reports from data currently within their insurance operations systems. Fulfilling the reporting requirements will require that they write programs to extract the data in the manner specified by the Department. There are no costs to the respondents, other than their time.

<table>
<thead>
<tr>
<th>CFR Section</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average response per respondent (in hours)</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>45 CFR 144.206</td>
<td>Insurers</td>
<td>30</td>
<td>6</td>
<td>45/60</td>
<td>135</td>
</tr>
</tbody>
</table>

We have determined that the estimated burden hours and burden costs of the proposed rule as required by Executive Order 12866, and the Regulatory Flexibility Act (RFA) are as follows: 30 respondents, 6 responses per respondent, average response per respondent (in hours) 45/60, and total burden hours 135.
partnership policies might increase by about 10 as more States obtain approved State plan amendments to operate State Long-Term Care Partnership Programs.

As we stated earlier, insurers participating in the original four Partnership Programs have been reporting data on policies sold and benefits used in the program for more than a decade. The reporting requirements in this final rule were designed to take advantage of data already available in insurer data sets. Insurers will not be asked to collect new data, but simply to recode existing data into a common format for submission to the Secretary. It is estimated that participating insurers will have to make a one-time investment to produce the computer programs necessary to compile the reports. Should the reporting requirement change in the future, there will also be a cost to make the necessary changes.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As stated above, this final rule will not have a substantial effect on State and local governments.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. As stated above, this final rule will not have a substantial effect on State and local governments.

List of Subjects in 45 CFR Part 144

Health care, Health insurance, Reporting and recordkeeping.

For the reasons stated in the preamble of this final rule, we are amending 45 CFR Subtitle A, Subchapter B, Part 144 as set forth below:

Subchapter B—Requirements Relating to Health Care Access

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

1. The authority citation for Part 144 is revised to read as follows:


2. A new Subpart B is added to read as follows:

Subpart B—Qualified State Long-Term Care Insurance Partnerships: Reporting Requirements for Insurers

Sec.

144.200 Basis.

144.202 Definitions.

144.204 Applicability of regulations.

144.206 Reporting requirements.

144.208 Deadlines for submission of reports.

144.210 Form and manner of reports.

144.212 Confidentiality of information.

144.214 Notifications of noncompliance with reporting requirements.

Subpart B—Qualified State Long-Term Care Insurance Partnerships: Reporting Requirements for Insurers

§ 144.200 Basis.

This subpart implements—

(a) Section 1917(b)(1)(C)(iii)(VI) of the Social Security Act, (Act) which requires the issuer of a long-term care insurance policy issued under a qualified State long-term care insurance partnership to provide specified regular reports to the Secretary.

(b) Section 1917(b)(1)(C)(v)(y) of the Act, which specifies that the regulations of the Secretary under section 1917(b)(1)(C)(iii)(VI) of the Act shall be promulgated after consultation with the National Association of Insurance Commissioners, issuers of long-term care insurance policies, States with experience with long-term care insurance partnership plans, other States, and representatives of consumers of long-term care insurance policies, and shall specify the type and format of the data to be reported and the frequency with which such reports are to be made. This section of the statute also provides that the Secretary provide copies of the reports to the States involved.

§ 144.202 Definitions.

As used in this Subpart—

Partner qualified policy refers to a qualified long-term care insurance policy issued under a qualified State long-term care insurance partnership. Qualified long-term care insurance policy means an insurance policy that has been determined by a State insurance commissioner to meet the requirements of sections 1917(b)(1)(C)(iii)(I) through (IV) and 1917(b)(5) of the Act. It includes a certificate issued under a group insurance contract.

Qualified State long-term care insurance partnership means an approved Medicaid State plan amendment that provides for the disregard of any assets or resources in an amount equal to the insurance benefit payments that are made to or on behalf of an individual who is a beneficiary under a long-term care insurance policy that has been determined by a State insurance commissioner to meet the requirements of section 1917(b)(1)(C)(iii) of the Act.

§ 144.204 Applicability of regulations.

The regulations contained in this subpart for reporting data apply only to those insurers that have issued qualified
§ 144.206 Reporting requirements.

(a) General requirement. Any insurer that sells a qualified long-term care insurance policy under a qualified State long-term care insurance partnership must submit, in accordance with the requirements of this section, data on insured individuals, policyholders, and claimants who have active partnership qualified policies or certificates for a reporting period.

(b) Specific requirements. Insurers of qualified long-term care insurance policies must submit the following data to the Secretary by the deadlines specified in paragraph (c) of this section:

(1) Registry of active individual and group partnership qualified policies or certificates. Insurers must submit data on—

(A) Any insured individual who held an active partnership qualified policy or certificate at any point during a reporting period, even if the policy or certificate was subsequently cancelled, lost partnership qualified status, or otherwise terminated during the reporting period; and

(B) All active group long-term care partnership qualified insurance policies, even if the identity of the individual policy/certificate holder is unavailable.

(ii) The data required under paragraph (b)(1)(i) of this section must cover a 6-month reporting period of January through June 30 or July 1 through December 31 of each year; and

(iii) The data must include, but are not limited to—

(A) Current identifying information on the insured individual;

(B) The name of the insurance company and issuing State;

(C) The effective date and terms of coverage under the policy;

(D) The annual premium;

(E) The coverage period;

(F) Other information, as specified by the Secretary in “State Long-Term Care Partnership Insurer Reporting Requirements.”

(2) Claims paid under partnership qualified policies or certificates. Insurers must submit data on all partnership qualified policies or certificates for which the insurer paid at least one claim during the reporting period. This includes data for employer-paid core plans and buy-up plans without individual insured data. The data must—

(i) Cover a quarterly reporting period of 3 months;

(ii) Include, but are not limited to—

(A) Current identifying information on the insured individual;

(B) The type and cash amount of the benefits paid during the reporting period and lifetime to date;

(C) Remaining lifetime benefits;

(D) Other information, as specified by the Secretary in “State Long-Term Care Partnership Insurer Reporting Requirements.”

§ 144.208 Deadlines for submission of reports.

(a) Transition provision for insurers who have issued or exchanged a qualified partnership policy prior to the effective date of these regulations.

The first reports required for these insurers will be the reports that pertain to the reporting period that begins no more than 120 days after the effective date of the final regulations.

(b) All reports on the registry of qualified long-term care insurance policies issued to individuals or individuals under group coverage specified in § 144.206(b)(1)(ii) must be submitted within 30 days of the end of the 6-month reporting period.

(c) All reports on the claims paid under qualified long-term care insurance policies issued to individual and individuals under group coverage specified in § 144.206(b)(2)(i) must be submitted within 30 days of the end of the 3-month quarterly reporting period.

§ 144.210 Form and manner of reports.

All reports specified in § 144.206 must be submitted in the form and manner specified by the Secretary.

§ 144.212 Confidentiality of information.

Data collected and reported under the requirements of this subpart are subject to the confidentiality of information requirements specified in regulations under 42 CFR Part 401, Subpart B, and 45 CFR Part 5, Subpart F.

§ 144.214 Notifications of noncompliance with reporting requirements.

If an insurer of a qualified long-term care insurance policy does not submit the required reports by the due dates specified in this subpart, the Secretary notifies the appropriate State insurance commissioner within 45 days after the deadline for submission of the information and data specified in § 144.208.